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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,117

12/30/2003

David M. Gravett

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVENUE, SUITE 5400
SEATTLE, WA 98104-7092

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,117	Applicant(s) GRAVETT ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10-12, 14-75, 84, 87-95, 98, 101-104, 106-112 and 127-141 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 15, 16, 22-74, 101, 103 and 104 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10, 14, 17-21, 75, 84, 87-95, 98, 102, 106-112 and 127-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to the claims filed 03/11/2008 have been entered, applicants have cancelled claims 4-9,96-97 and 99-100, entered new claims 130-141 and amended claims 1,84,88-93,98,106 and 110. Any objection/rejection from the previous office action filed 09/26/2007 not addressed below has been withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,10,14,17-21,75, 84,87-95,98,101-102,106-112, 127-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 6,312,725) in view of Shih et al. (US 6,287,588), for the reasons set forth in the office action filed 09/11/2007, a new reasoning for the rejection of the amended claims and new claims 131-141 was necessitated by amendment.

Regarding applicants amendments to claim 1 and new claim 134 which attempt to limit the gel based on the process to produce the gel in which the components are mixed in a first buffer solution and then the second buffer solution is then added, since the claims are drawn to a drug delivering composition the combination of Wallace and Shih obviously discloses applicants claimed invention, thus the rejection still stands. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

Art Unit: 1618

unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Similarly the limitation within new claim 130 that the first and second component are in powder form is considered met since they are both added to buffer solutions to form the same composition as Wallace and Shih, there is no patentable distinction between applicants claims and the cited prior art. Regarding claims 131 and 135 Wallace discloses the use NHS. Regarding claims 132, 133 and 138 Wallace discloses the use of pentaerythritol (PEG) ether tetra-sulfhydryl and pentaerythritol (PEG) ether tetra-succinimidyl glutarate and Shih discloses the use of PEG-PDLLA encapsulating paclitaxel, the copolymers MW is between 300 and 20,000 Daltons. See col 5 lin 43-49 and col 7 lin 33-52 of Shih. It would have been obvious from the disclosure of Shih to vary the length of the hydrophilic PEG moiety depending upon the desired hydrophilicity of the microparticle. The other new claims (136-141) essentially duplicate previous limitations within the prior claim sets but are dependent upon new independent claim 134, thus for the reasons set forth in the previous office action claims 136-141 are obvious in view of the cited art.

Response to Arguments

Applicant's arguments filed 03/11/2008 have been fully considered but they are not persuasive. Applicants assert there is no sufficient suggestion or motivation to combine the references to arrive at amended claim 1 because Wallace does not disclose or suggest hydrophobic drugs or hydrophobic drugs incorporated within polymeric microspheres and one with skill in the art would not expect that the hydrophobic agents of Shih would be compatible with Wallace's hydrophilic gel.

Applicants further assert that Shih describes a completely different gel system than Wallace in which the gels are amphiphilic containing hydrophobic blocks to contain hydrophobic drugs. Applicants further assert that examiners conclusion of obviousness is based upon improper hindsight analysis.

The relevance of these assertions is unclear. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Clearly the examiner noted in the last action that Wallace does not teach the encapsulation of hydrophobic drugs within microspheres if it did the reference would be a 102 type rejection on its own merit, thus it was combined with the Shih reference. It is also noted by the examiner that teaching, suggestion or motivation to combine is not the only consideration to make within a 103(a) obviousness rejection, the recent court ruling of *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007), recently upheld this view by the office. Regardless as noted in the last action there would be clear motivation to combine the two gel systems disclosed in the references above in order to formulate a gel system with the disclosed advantageous of each individual gel within the prior art. The advantage of such a composition would be a controlled release of drug using the microspheres disclosed within Shih for tissue treating applications requiring rapid adhesion by polymer gels such as those gels of Wallace. One with skill in the art would have a reasonable expectation of success in combining the two references above

because both are related to the same field of endeavor, biocompatible gels that controllably release active agents and the combination would have yielded predictable results to one of ordinary skill in the art. It also would have been obvious to one of ordinary skill in the art at the time of applicants invention that since the block copolymers of Shih have a hydrophilic block (PEG) that surrounds the hydrophobic interior block and drug it would be capable of being combined with the hydrophilic gel system of Wallace because it is well known in the art that two hydrophilic gels could be combinable based upon their similar solubility properties. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). But see *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) ("Based upon the prior art and the fact that each of the three components of the composition used in the claimed

method is conventionally employed in the art for treating cooling water systems, the board held that it would have been *prima facie* obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive.... Appellant argues... hindsight reconstruction or at best,... obvious to try'.... We agree with appellant."). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

<i>Application Number</i> 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/749,117	GRAVETT ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	